



**ENVIRONMENTAL PROTECTION AGENCY**

**[EPA-HQ-RCRA-2007-0932, FRL- 8936-01-OLEM]**

**Agency Information Collection Activities; Proposed Collection; Comment Request;**

**Management Standards for Hazardous Waste Pharmaceuticals title of ICR, EPA ICR No. 2486.03, OMB Control No. 2050-0212**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** The Environmental Protection Agency (EPA) is planning to submit the information collection request (ICR), Management Standards for Hazardous Waste Pharmaceuticals (EPA ICR No. 2486.03, OMB Control No. 2050-0212) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act (PRA). Before doing so, the EPA is soliciting public comments on specific aspects of the proposed information collection as described in

**Supplementary Information.** This is a proposed extension of the ICR, which is currently approved through May 31, 2022. An Agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

**DATES:** Comments must be submitted on or before **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

**ADDRESSES:** Submit your comments, referencing by Docket ID No. EPA-HQ-RCRA-2007-0932, to: (1) EPA online using [www.regulations.gov](https://www.regulations.gov) (our preferred method), by email to [rcra-docket@epa.gov](mailto:rcra-docket@epa.gov), or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave., NW, Washington, DC 20460, and (2) OMB via email to [oira\\_submission@omb.eop.gov](mailto:oira_submission@omb.eop.gov). Address comments to OMB Desk Officer for EPA.

EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity,

threats, information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

**FOR FURTHER INFORMATION CONTACT:** Kristin Fitzgerald, Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460; telephone number: 202-566-0512; email address: [fitzgerald.kristin@epa.gov](mailto:fitzgerald.kristin@epa.gov).

**SUPPLEMENTARY INFORMATION:** Supporting documents which explain in detail the information that the EPA will be collecting are available in the public docket for this ICR. The docket can be viewed online at [www.regulations.gov](http://www.regulations.gov). Out of an abundance of caution for members of the public and our staff, the EPA Docket Center and Reading Room is closed to the public, with limited exceptions, to reduce the risk of transmitting COVID-19. Our Docket Center staff will continue to provide remote customer service via email, phone and webform. For further information about the EPA's public docket, Docket Center services and the current status, please visit us online at <https://www.epa.gov/dockets>. The telephone number for the Docket Center is 202-566-1744.

Pursuant to section 3506(c)(2)(A) of the PRA, the EPA is soliciting comments and information to enable it to: (i) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility; (ii) evaluate the accuracy of the Agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (iii) enhance the quality, utility, and clarity of the information to be collected; and (iv) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses. The EPA will consider the comments received and amend the ICR as appropriate. The final ICR package will then be submitted to OMB for review and approval. At that time, the EPA will issue another Federal Register notice to announce the

submission of the ICR to OMB and the opportunity to submit additional comments to OMB.

*Abstract:* Some pharmaceuticals are regulated as hazardous waste under the Resource Conservation and Recovery Act (RCRA) when discarded. This final rule added regulations for the management of hazardous waste pharmaceuticals by healthcare facilities and reverse distributors. Healthcare facilities (for both humans and animals) and reverse distributors now manage their hazardous waste pharmaceuticals under a new set of sector-specific standards in lieu of the existing hazardous waste generator regulations. These regulations are found in 40 CFR 266, Subpart P, and are mandatory. The new requirements include labeling containers holding non-creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals with the words “Hazardous Waste Pharmaceuticals”. Healthcare facilities and reverse distributors must also track or manage rejected shipments by sending a copy of the manifest to the designated facility that returned or rejected the shipment. Additionally, healthcare facilities and reverse distributors must submit exception reports for a missing copy of a manifest. Reverse distributors are required to amend their contingency plan under 40 CFR 262 Subpart M. A reverse distributor must submit an unauthorized hazardous waste report if it receives waste it is not authorized to receive.

*Form Numbers:* None.

*Respondents/affected entities:* Entities potentially affected by this action are the private sector.

*Respondent’s obligation to respond:* mandatory (RCRA Section 3001)

*Estimated number of respondents:* 13,373

*Frequency of response:* annual

*Total estimated burden:* 43,577 hours. Burden is defined at 5 CFR 1320.03(b)

*Total estimated cost:* \$2,543,409, which includes \$2,543,409 annualized labor costs and \$0 annualized capital or O&M costs.

*Changes in Estimates:* The burden hours are expected to decrease as some of the burden associated with the rule have been incorporated into other existing ICRs.

Dated: October 5, 2021.

Carolyn Hoskinson, Director,

Office of Resource Conservation and Recovery.

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